Aravind Eye Hospital
1 Anna Nagar
Madurai - 625 020, India

Phone : +91 - 452 - 535573 or 537580
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K024091 (1 of 2)

510(K) Summary

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

FEB 2 8 2003

The assigned 510 (k) number is:_____.

Applicant:

Aurolab,
Aravind Eye Hospital
LAICO Building
72 KK Salai,
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Madurai – 625020,
India.

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Contact Person:

In India	In United States
Dr.P.Balakrishnan, Managing Director, Aurolab, Aravind Eye Hospital LAICO Building 72 KK Salai, Gandhi Nagar, Madurai – 625020, India. Tel: 91 – 452 – 535573 Fax: 91 – 452 – 535274 Email: aurolab@aurolab.com bala@aurolab.com	**U.S.Representative:** Michael G. Price President, Visionary Medical Supplies, Inc. 6441 Enterprise Lane, Suite 214 Madison, WI 53719 Phone: 608-270-3880 Fax: 608-270-3882 Email: visionarymedical@earthlink.net

Date of 510 (k) summary preparation: November 11, 2002

K024091 (P. 2 of 2)

Trade name: ------

Common name: Suture, nonabsorbable, Silk

Predicate devices:

Nonabsorbable Silk sutures manufactured by Aurolab are equivalent to Ethicon silk nonabsorbable sutures.

Device description:

This Silk suture is a nonabsorbable, sterile, surgical sutures composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae.Those dyed black are dyed with Hematein (logwood) black and the logwood extract conforms with 21 CFR 73.1410 and does not exceed 1.0% (W/W) of Suture.

This nonabsorbable suture is compossed of silk filaments that are braided or twisted in a suitable construction for the intended size to meet current USP specification.

This suture may be uncoated or have a silicone coating ,a paraffin wax coating , or a natural gum coating (Virgin Silk) . This sutures come with needles attached.

Intended use:

Nonabsorbable Silk suture manufactured by Aurolab is indicated for use in general soft tissue approximation and/ or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Performance tests to demonstrate substanital equivalency:

To establish the technical equivalency of Non absorbable sutures manufactured by Aurolab with the predicate devices, tests according to methods presented in United States Pharmacopoeia (U.S.P) were conducted for diameter, tensile strength and Suture- needle attachment.

The test results shows that Aurolab devices tested meet USP standards and are technically equivalent to the predicate devices tested.

Dr.P.Balakrishnan, M.D., Aurolab

November 11, 2002,
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

Aurolab
c/o Visionary Medical Supplies
Michael G. Price
President
6441 Enterprise Lane, Suite 214
Madison, Wisconsin 53719

Re: K024091
Trade/Device Name: Silk Sutures
Regulation Number: 878.5030
Regulation Name: Nonabsorbable silk surgical suture
Regulatory Class: Class II
Product Code: GAP
Dated: December 6, 2002
Received: December 11, 2002

Dear Mr.Price:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Page 1 of 1

510(k) Number (if known): K024091

Device Name: Suture, nonabsorbable, Silk

Trade name: ----------

Common name: Suture, nonabsorbable, Silk

Instructions for Use:

Aurolab nonabsorbable Silk suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS
LINE- CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaluation
(ODE)

(Optional Format 3-10-98)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024091